# BISMATROL- bismuth subsalicylate tablet, chewable Preferred Pharmaceuticals Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

#### **Major Bismatrol Chewable Tablets**

#### **Active ingredient (in each tablet)**

Bismuth subsalicylate 262 mg (total salicylate 102 mg per tablet)

#### **Purpose**

Upset stomach reliever and anti-diarrheal

#### Uses

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

#### **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. when using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Contains salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

# Do not use if you have

- bloody or black stools
- an ulcer
- a bleeding problem

# Ask a doctor before use if you have

- fever
- mucus in the stool

### Ask a doctor or pharmacist before use if you are taking any drug for

- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

#### When using this product

a temporary, but harmless darkening of the stool and/or tongue may occur.

#### Stop use and ask a doctor if

- symptoms get worse
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

#### If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children**. In case of overdose, get medical help or contact a Poison Control Center immediately.

#### **Keep Out of Reach of Children**

**Keep Out of Reach of Children -** In case of overdose, get medical help or contact a Poison Control Center immediately

#### **Directions**

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not take more than 8 doses (16 tablets) in 24 hours
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration caused by diarrhea.

#### Other information:

#### each tablet contains:

- sodium less than 1 mg
- salicylate 102 mg
- very low sodium
- avoid excessive heat (over 104°F or 40°C)
- TAMPER EVIDENT:Do not use if individual compartments are torn or missing.

### **Inactive ingredients**

calcium carbonate, D&C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium.

## **Principal Display Panel**

**MAJOR** 

NDC 68788-7140-3

Bismatrol Chewable Tablets

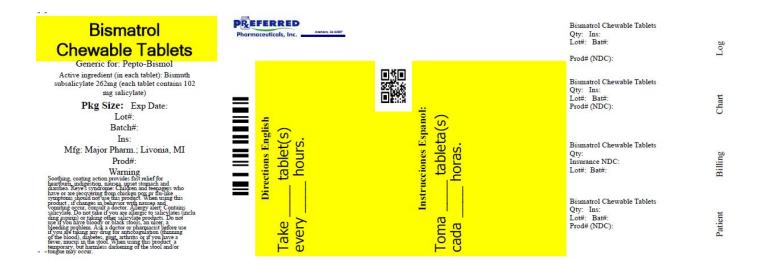
Soothing, coating action provides

fast relief for heartburn, indigestion, nausea, upset stomach and diarrhea

COMPARE TO THE ACTIVE INGREDIENT IN PEPTO-BISMOL®

#### Relabeled By: Preferred Pharmaceuticals Inc.

30 chewable tablets



#### **BISMATROL**

bismuth subsalicylate tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7140(NDC:0904-1315)	
Route of Administration	ORAL			

Ingredient Name Basis	of Ctropath	C+ +1-
	or strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - BISMUTH CATION - SUBSALICYLATE (UNII: ZS9CD118YE)		262 mg

Inactive Ingredients				
Ingredient Name	Strength			
CALCIUM CARBONATE (UNII: H0G9379FGK)				
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 30WL53L36A)				
STARCH, CORN (UNII: O8232NY3SJ)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				

Product Characteristics				
Color	pink	Score	no score	
Shape	ROUND	Size	17mm	
Flavor		Imprint Code	GDC122	
Contains				

I	Packaging				
4	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68788- 7140-3	5 in 1 CARTON	04/19/2018		
1	L	6 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part335	04/19/2018		

# **Labeler - Preferred Pharmaceuticals Inc. (791119022)**

# **Registrant - Preferred Pharmaceuticals Inc. (791119022)**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7140)	

Revised: 3/2021 Preferred Pharmaceuticals Inc.